DEPARTMENT **OF HEALTH & HUMAN** SERVICES

HFD-613

Food and Drug Administration
Rockville MD 20857

NDA 19-970/S-010

APR 21 1999

Baxter Healthcare Corporation
Attention: Ms. Marcia Marconi
Route 120 & Wilson Road
Round Lake, IL 60073-0490

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated February 17, 1999, received February 19, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitroglycerin in 5% Dextrose Injection.

This supplemental new drug application provides for final printed labeling revised by adding the following bolded statement as the first paragraph under **WARNINGS:**

> Amplification of the vasodilatory effects of Nitroglycerin by sildenafil can result in severe hypotension. The time course and dose dependence of this interaction have not been studied. Appropriate supportive care has not been studied, but it seems reasonable to treat this as a nitrate overdose, with elevation of the extremities and with central volume expansion.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling included in your February 17, 1999 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 2 1 CFR 3 14.80 and 314.81.

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(301) 594-5300

Sincerely yours,

Raymond J. M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research